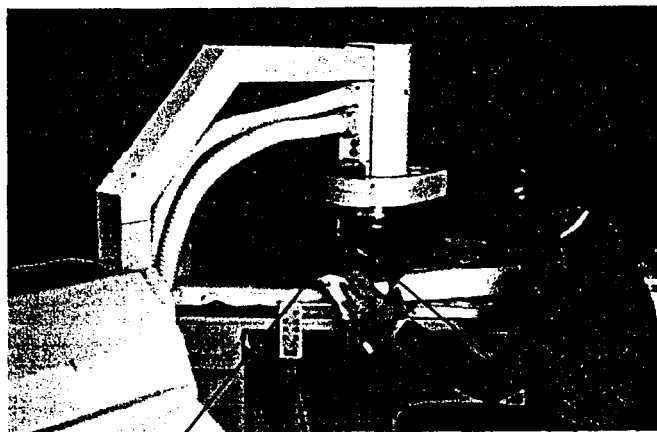


## Patient Information

### Extracorporeal Shock Wave (ESW) Treatment for Tennis Elbow (Chronic Lateral Epicondylitis) with the HealthTronics OssaTron®



OssaTron  
Shock head

Treated elbow

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### ***What is extracorporeal shock wave (ESW) treatment?***

The OssaTron is a shock wave generator, very similar to the shock wave devices used to treat kidney stones without surgery. "Extracorporeal" means "outside the body". Shock waves are created by very strong sound (acoustic) energy. Your shockwave treatment will be performed with a device called the OssaTron.

### ***How is the OssaTron procedure performed?***

The shock waves are created by a spark plug that is enclosed in a soft plastic dome filled with water. An electrical charge is sent to the spark plug, which creates a shockwave that expands into the surrounding water. During shockwave treatment, this dome is placed closely against the elbow so that the shock waves pass through the dome to the elbow. Shockwave treatment with the OssaTron is for patients who can tolerate general anesthesia or local anesthesia, which requires an injection by a needle in your arm prior to the shockwave procedure. Shockwave treatment with the OssaTron is painful. Shockwave treatment with the OssaTron is for patients who can tolerate hearing protection to reduce the risk of hearing impairment due to the sound of the OssaTron. Shockwave treatment has recently been found to be effective in treating tennis elbow, a condition that causes pain in the elbow of the affected arm and is sometimes called "chronic lateral epicondylitis".

### ***What other treatments are available for treating tennis elbow?***

Doctors know that many people who have elbow pain get better with time, even with no treatment. Many other people get better after trying one or several of the following treatments, which include:

- Rest
- Application of heat or cold
- Physical conditioning exercises
- Physical therapy, including ultrasound therapy
- Over-the-counter pain relievers, such as aspirin or Tylenol (acetaminophen)
- Prescription pain relievers
- Non-steroidal anti-inflammatory medications (NSAID's), such as Advil (ibuprofen) or Aleve (naproxen)
- Cortisone injections (steroid)

- **Infection involving the body as a whole (Systemic infection)**

Your doctor can provide you with additional information about these conditions, and how they might affect the decision to perform shockwave treatment.

***What are the side effects and complications that could happen?***

- The shockwave treatment may cause skin reddening or bruising of the treated elbow, which usually clears within a few days. You may also have a reaction to the anesthesia that is administered.
- The shockwave treatment may not help elbow pain in your case. You may have episodes of pain similar to the pain you had before treatment. The pain may continue for a few days to a few weeks after treatment.

***What will happen on the day of the shockwave treatment?***

Your doctor will probably ask you to come to the hospital or surgery center a few hours before the shockwave treatment is scheduled. You should wear a short sleeve shirt or loose fitting clothing that can easily be rolled up past your affected elbow. Otherwise, you may be asked to change from your own clothes into a hospital gown. The staff may take your temperature, pulse and blood pressure and ask you some questions about your general health. They will also make sure you have signed a consent form for the shockwave treatment.

The shockwave treatment may cause some pain or discomfort, so an anesthetic is commonly given before the procedure. Usually, this will be a local/regional anesthetic performed by using a needle in the arm or a general anesthetic. You will be asked to rest comfortably on your back while your doctor holds your arm up to the OssaTron shock head as shown on the front of this pamphlet. Shockwave treatment with the OssaTron is for patients who can tolerate hearing protection to reduce the risk of hearing impairment due to the sound of the OssaTron.

A shockwave treatment for tennis elbow usually takes about 30 minutes. The shockwave treatment is performed as an outpatient procedure; no overnight hospital stay is necessary.

***What will happen after the shockwave treatment?***

Immediately after treatment, you will stay at the hospital or surgery center until the anesthetic wears off enough so it is safe for you to leave. Your doctor will probably ask you to restrict stressful activity involving the treated elbow for 4 weeks after treatment. "Stressful activity" may include doing heavy housework or yard work, and participating in sports.

Some patients need a mild pain medication following shockwave treatment. Although some patients in the clinical study felt immediate relief from pain after the shockwave treatment, it is more common for it to take up to 6 weeks for pain relief to begin.

***What are the expected results from shockwave treatment?***

In the OssaTron clinical study, patients with chronic lateral epicondylitis were graded "Success" or "Fail" according to 3 measurements. 1) The doctor graded the amount of pain with pressure on the elbow; 2) the patient graded the amount of pain during activity and 3) the patient reported the amount of pain medication he or she needed for elbow pain.

Percentage of Patients with  
Successful Outcome at 8 weeks-All Subjects Randomized

Results at 8 Weeks		
Measurement	OssaTron Treatment (n=93)	Placebo Treatment (n=90 )
Investigator Assessment	45(48%)	26(29%)
Self Assessment, Pain during activity	51(55%)	37(41%)
Medication Use	75(81%)	63(70%)
Composite: All 3 Components	33(35%)	20(22%)

Your doctor will ask you to return to the office for a follow up visit, probably at about 6 or 8 weeks after your OssaTron treatment. Please check with your doctor about this follow up visit.

***I have more questions about shockwave treatment for elbow pain. How can I get more information?***

In order to use the OssaTron to treat tennis elbow, your doctor had to complete a specialized training program. The training program not only allowed your doctor to learn how to perform the shockwave treatment, but it also included information about shock wave energy in general, and information from the OssaTron clinical study. Therefore, your doctor is the best person to talk to if you have any questions or concerns about shockwave treatment for chronic lateral epicondylitis with the OssaTron.

HealthTronics Surgical Services, Inc.  
1841 W. Oak Parkway, Suite A  
Marietta, GA 30062  
Telephone numbers  
1-770-419-0691 / 1-800-464-3795